EPA REGISTRATION NUMBER 71185-4 – VOL. 2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 23, 2019

James Messina
Authorized Agent for Geo Logic Corporation
c/o Exponent
1150 Connecticut Ave, NW
Suite 1150
Washington, DC 20036

Subject: PRIA CSF Amendment – Alternate CSF 4; adding new unregistered source of active ingredient
Product Name: EAC Streptomycin Manufacturing Use Product
EPA Registration Number: 71185-4
Application Date: March 12, 2018
Decision Number: 539440

Dear Mr. Messina:

The Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 01/15/2016
- Alternate CSF 1 dated 01/15/2016
- Alternate CSF 2 dated 01/15/2016
- Alternate CSF 3 dated 01/15/2016
- Alternate CSF 4 dated 10/31/2017

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Fatima Sow by phone at (703) 347-8308, or via email at sow.fatima@epa.gov.

Sincerely,

Hope Johnson, Product Manager 21
Fungicide Branch
Registration Division (7505P)
Office of Pesticide Programs

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEE

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

DP Barcode No.: D446895 File Symbol No.: 71185-4 Decision No.: 539440
PC Code: 006310 Company Name: Geo Logic Corp.
Food Use: No Action Code: R 351 Product Name: EAC Streptomycin Manufacturing Use Product

Date: April 17, 2019

SUBJECT: Product Chemistry Review of the Proposed Manufacturing Use Product, EAC Streptomycin Manufacturing Use Product

FROM: Bruce F. Kitchens, Chemist
Chemistry, Inert and Toxicology Assessment Branch/RD (7505P)
Registration Division (7505P)

Bruce F. Kitchens
S Bruce
4-17-19

TO: RM #21, Hope Johnson/Fatima Sow
Fungicide Branch
Registration Division (7505P)

INTRODUCTION:

The registrant, Geo Logic Corporation, is applying to amend the registered manufacturing use product, EAC Streptomycin Manufacturing Use Product. This amendment is the result of the use of an alternate production facility. The active ingredient in this product is Streptomycin sulfate at a label nominal concentration of 88.0% a.i. This product is intended for use in the manufacture of pesticide end-use products. In support of this request, the registrant has submitted an alternate formula (#4) Confidential Statement of Formula (CSF) dated 31 Oct 2017 and product chemistry data contained in MRID#s 504733-01. The Chemistry, Inerts and Toxicology Assessment Branch (CITAB) has been asked to review this submission.

SUMMARY OF FINDINGS:

CITAB has reviewed this submission and reports the following findings:

1. This product is produced from an integrated formulation system. This means that the product is the result of intended chemical reactions.

2. All impurities have been assayed and identified by the registrant. The registrant has not declared any impurities of toxicological concern in this product. All impurities have a nominal concentration and upper certified limits.

3. The nominal concentration of the active ingredient listed on the proposed alternate CSF is 90.5% and falls within the certified limits established at registration.

4. The active ingredient's certified limits as proposed on the alternate CSF #4 are acceptable.

5. The alternate production site for Streptomycin Manufacturing Use Product is:

[redacted]

CONCLUSIONS:

CITAB has reviewed this submission and concludes the following:

1. The proposed alternate formula CSF #4 for the manufacturing use product, EAC Streptomycin Manufacturing Use Product dated 31 Oct 2017 is acceptable.

2. This submission satisfies the data requirements as specified in 40 CFR 158.320, 158.325, 158.330, 158.340, 158.345, 158.350, and 158.355 with respect to product identity and composition, description of materials used to produce the product, description of production process, discussion of formation of impurities, preliminary analysis, certified limits, and enforcement analytical method.

3. The proposed alternate formula #4 for the manufacturing use product, EAC Streptomycin Manufacturing Use Product meets the criteria specified in 40 CFR 152.43 with respect to alternate formulations.

830.1550. Product Identity & Composition:

Common Name: Streptomycin sulfate

Chemical Name (CAS): N/A
(IUPAC): 2-[(1R,2R,3S,4R,5R,6S)-3-diaminomethylideneamino)-4-[(2S,3S,4S,5R)-3-[(2R,3R,4R,5S,6R)-4,5-dihydroxy-6-(hydroxymethyl)-3-(methylamino)oxan-2-yl]oxy-4-formyl-4-hydroxy-5-methyloxolan-2-yl]oxy-2,5,6-trihydroxycyclohexyl]guanidine

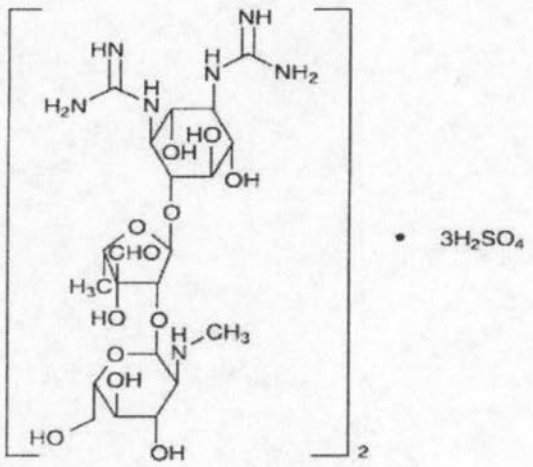
CAS No.: 3810-74-0

PC Code No.:

Empirical formula: $(C_{21}H_{39}N_7O_{12})_2 \cdot 3H_2SO_4$

Molecular Weight: 1,457 g/mole

Structural formula:



DP Barcode No.: D446895 File Symbol No.: 71185-4 Decision No.: 539440
PC Code: 006310 Company Name: Geo Logic Corp.
Food Use: No Action Code: R 351 Product Name: EAC Streptomycin Manufacturing Use Product

Table 1. Manufacturing and Impurity Data for EAC Streptomycin Manufacturing Use Product

GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and Composition	504733-01	A	The nominal concentration of the active ingredient 90.50% is supported by the 5-batch analysis and is not the same as the label claim nominal concentration but falls within the certified limits established at registration. [redacted] impurities (≥ 0.1%) including [redacted] are listed on the CSF.
8301600	Description of Materials Used to Produce the Product	504733-01	A	The product specification sheets (MSDS) for all the starting materials have been provided by the registrant
830.1620	Description of Production Process	504733-01	A	The AI was produced in a four-step integrated process. The production process has been described in full detail. The reaction conditions, amounts of chemicals in each step, duration of time, and the yields in each step have been provided. The QA steps involved in each step have been described.
830.1670	Discussion of Formation of Impurities	504733-01	A	The registrant has provided the complete mechanisms of formation, quantification and identification of all the impurities present at the levels of ≥ 0.1%. [redacted] impurities have been listed on the CSF including [redacted]. No toxic impurity was reported during the synthesis.
830.1700	Preliminary Analysis	504733-01	A	The registrant has provided 5 batch analysis for the TGAI. The AI & impurities were quantified by HPLC/UV. The five-batch analysis supported the CSF for basic formulation.
830.1750	Certified Limits	504733-01	A	The proposed certified limits for the AI & for the impurities are based on the five batch analytical results.
830.1800	Enforcement Analytical Method	504733-01	A	An HPLC/UV method was used for the determination of the active ingredient content in the MUP. The active ingredient was identified by TLC. System suitability was evaluated.

A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress or need upgrade; U = Up-grade (additional information required

Product ingredient source information may be entitled to confidential treatment

DP Barcode No.: D446895 File Symbol No.: 71185-4 Decision No.: 539440
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CONFIDENTIAL APPENDIX

Results of the 5-batch analysis are provided in the following table:

Manufacturing process information may be entitled to confidential treatment

Reginald Coler

From: notification@pay.gov
Sent: Thursday, March 8, 2018 3:05 PM
To: James Messina
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 2689JIB9
Agency Tracking ID: 75440462312
Transaction Type: Sale
Transaction Date: 03/08/2018 03:04:59 PM EST

Account Holder Name: Taw Richardson

Transaction Amount: $3,307.00
Card Type: Discover
Card Number: **********4555

Registration Number: 71185-4
Company Name: Geo Logic Corporation
Company Number: 71185
Action Code: R351

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA United States **Environmental Protection Agency** Washington, DC 20460

☐ **Registration** ☒ **Amendment** ☐ **Other**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 71185-4
2. EPA Product Manager: Hope Johnson
3. Proposed Classification: ☒ None ☐ Restricted
4. Company/Product (Name): EAC Streptomycin Manufacturing Use Product
5. PM# 21
5. Name and Address of Applicant *(Include ZIP Code)*: Geo Logic Corporation, P.O. Box 3091, Tequesta, FL 33469
☐ *Check if this is a new address*
6. **Expedited Review**. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section II

☒ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated
☐ "Me Too" Application
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Submission of an amendment to add a new alternate source #4.

Section III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) Plastic Bag
***Certification must be submitted**	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Package wgt. / No. per Container	

3. Location of Net Contents Information: ☐ Label ☐ Container
4. Size(s) Retail Container
5. Location of Label Directions: ☐ On Can ☐ On Labeling accompanying product
6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section IV

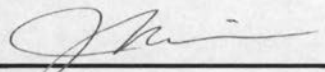
1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
James Messina	Authorized Representative	202-772-4932

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature BY: 
3. Title: Authorized Representative
4. Typed Name: James Messina
5. Date: December 21, 2017

DOCUMENTUM

Pages 10-12 Claimed confidential by submitter

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M STREET, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Geo Logic Corporation P.O. Box 3091 Tequesta, FL 33469	71185-4
Active Ingredient(s) and/or representative test compound(s) Streptomycin	Date December 21, 2017
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Outdoor food-use	Product Name EAC Streptomycin Manufacturing Use Product

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulators Exemption Statement (EPA Form 8570-27)

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose)	☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method, or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA

SECTION III: CERTIFICATION

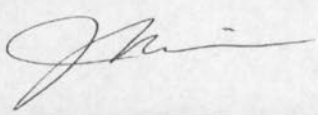
I certify that this application for registration, this form for reregistration or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitted to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under applicable law.

Signature	Date	Typed or Printed Name and Title
	December 21, 2017	James Messina Authorized Representative

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